

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,872	09/28/2001	Mark Roby	11396 (203-3054)	3462
Patent Counse	7590 01/03/200	EXAMINER		
US Surgical, Div of TYCO HEALTHCARE GROUP LP 150Glover Avenue Norwalk, CT 06856			CAMERON, ERMA C	
			ART UNIT	PAPER NUMBER
			1762	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/03/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

·	Application No.	Applicant(s)				
	09/965,872	ROBY, MARK				
Office Action Summary	Examiner	Art Unit				
	Erma Cameron	1762				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on 16 Oc	ctoher 2006					
· · · · · · · · · · · · · · · · · · ·	<u>.</u>					
·-	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
closed in accordance with the practice under Lx parte Quayre, 1930 C.D. 11, 433 C.G. 213.						
Disposition of Claims						
4) Claim(s) 1-17 is/are pending in the application.)⊠ Claim(s) <u>1-17</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdraw	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-17</u> is/are rejected.						
7) Claim(s) is/are objected to.		•				
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner	•					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
•						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:					

Art Unit: 1762

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-3, 5-12, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamora et al. (6,613,432) in view of Totakura (5,383,903).

Zamora teaches a method of coating blood- and tissue-contacting medical substrates by plasma polymerizing a hydrocyclosiloxane monomer, meeting the formula of Applicant, thereon (abstract; col. 4, lines 30-40). Zamora also teaches the use of alkylene oxide as a further layer (see below for details).

Zamora does not specifically teach coating sutures. However, Zamora teaches that his coating is suitable on temporarily implantable medical substrates which contact blood and tissue that may be made of polymers, such as polyethylene (col. 10, lines 9-13). This teaching is inclusive of sutures.

Additionally, Totakura is cited for teaching a method of coating polyethylene or polypropylene (both polyolefins) sutures with siloxane and alkylene oxide (abs; col. 2, lines 50). Since Zamora and Totakura both teach coating blood- and tissue-contacting medical substrates made of polyethylene with siloxane and alkylene oxide coatings and since Totakura teaches that such coatings are placed on sutures, Totakura would have reasonably suggested coating sutures by the method of Zamora. It would have been obvious to one of ordinary skill in the art to use the teachings of Totakura in the method of Zamora to provide Zamora with another suitable medical substrate for coating by the method of Zamora.

Application/Control Number: 09/965,872

Art Unit: 1762

Regarding claims 2 and 11, Zamora teaches the specific hydrocyclosiloxanes claimed (col. 6, lines 1-7).

Regarding claims 2, 3, 5, 6, 12, 14, and 15 Zamora teaches that the coating further comprises an amine group introduced by plasma polymerization of a gas containing the monomer N-trimethylsilyl-allylamine (col. 5, lines 9-18; col. 14, line 48).

Regarding claims 7-8 and 16-17, Zamora teaches that the amine-grafted hydrocyclosiloxane membranes may be reacted with carbonate polyoxyalkylenes, such as polyoxyethylene bis-(N-hydroxybenzotriazolyl) carbonate (col. 7, line 40; col. 15, lines 9-30).

Regarding claim 9, both references teach polyethylene substrates and Totakura teaches sutures made of polypropylene, both well-known polyolefins. It would have been obvious to use the polypropylene of Totakura in the method of Zamora as a suitable polyolefin for coating with siloxanes and alkylene oxides.

Response to Arguments

The applicant has argued in the 10/16/2006 amendment that neither Zamora not Totakura discloses nor suggests improving fray resistance. It is the examiner's position that improvement in the fray resistance is inherent to the coating being used.

Application/Control Number: 09/965,872 Page 5

Art Unit: 1762

4. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamora in view of Totakura as applied to claims 1-3, 5-12, and 14-17 above, and further in view of Hu (5,463,010).

Zamora in view of Totakura teach that which is disclosed above, namely, plasma polymerizing a suture with the hydrocyclosiloxane monomers and then plasma grafting N-trimethylsily-allylamine monomers thereto. What this combination fails to teach is the plasma co-polymerization of the two.

Hu teaches coating polypropylene fibers or other medical devices which come into contact with blood with a coating formed by plasma co-polymerization of the same hydrocyclosiloxane and N-trimethylsilyl-allylamine monomers as Zamora. Since Zamora in view of Totakura teach plasma grafting one monomer onto the other and Hu teaches plasma co-polymerizing the two monomers together on similar substrates for use in similar applications, Hu would have reasonably suggested to one of ordinary skill in the art to interchange the plasma grafting of Zamora in view of Totakura with his copolymerization method with the expectation of similar and successful results on similar substrates for use in the body for contact with blood and tissue.

Response to Arguments

The applicant has argued in the 10/16/2006 amendment that Hu does not disclose or suggest improving fray resistance. It is the examiner's position that improvement in the fray resistance is inherent to the coating being used by the combination of the three references.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 2 and 11 cite both a hydrocyclopentasiloxane and a cyclopentasiloxane, as well as both a hydrocyclohexasiloxane and a cyclohexasiloxane. The same is true at 12:12-17. It is not clear if different compounds are meant, or if one of the pair of terms is incorrect. In addition, the hexa compound is listed as substituted at both position 6 and 7.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 8. Claims 2, 7, 11 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- a) Claims 2 and 11: cite both a hydrocyclopentasiloxane and a cyclopentasiloxane, as well as both a hydrocyclohexasiloxane and a cyclohexasiloxane. It is not clear if different compounds are meant, or if one of the pair of terms is incorrect.
- b) Claims 2 and 11: the hexa compound is listed as substituted at both position 6 and 7.
- c) Claim 7 and 16, definition of R2, R3, R4: it is not clear how an alkylene group can be "about" 2 to "about" 3 carbon atoms. It would appear that these should be whole numbers.

Specification

9. The disclosure is objected to because of the following informalities:

Typo at 16:17.

Art Unit: 1762

Appropriate correction is required.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erma Cameron whose number is (571) 272-1416. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERMA CAMERON
PRIMARY EXAMINER

Erma Cameron Primary Examiner Art Unit 1762

December 26, 2006